



Office of Agricultural Affairs  
U.S. Embassy, Paris

## Agricultural Biotechnology in the United States Newsletter - November 2008

**To our readers:** We in the Office of Agricultural Affairs of the U.S. Embassy in Paris would be happy that you inform us of your visits to the United States, so that we can help you organize your meetings and your administrative procedures. Please do not hesitate to share any questions with us on these issues as we are here to facilitate these exchanges!

### 1. U.S. Policy:

#### USDA's Proposed Rule for Biotech Regulations<sup>1</sup>

On October 6, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) proposed to revise existing regulations regarding the importation, interstate movement and environmental release of certain genetically engineered (GE) organisms under the Plant Protection Act (PPA) of 2000. These proposed revisions to the regulations are in response to emerging trends in biotechnology. New regulations will address the current and future needs of the agency and provide a high level of environmental protection. The proposed changes will also improve regulatory processes so they are more transparent to stakeholders and the public, make more efficient use of agency resources and eliminate unnecessary regulatory burdens. The proposed rule also addresses several provisions from the 2008 Farm Bill regarding the improvement of the management and oversight of GE organisms regulated under the PPA of 2000. This proposal does not cover vertebrate animals. The proposed regulations would also establish a new petition procedure for APHIS to approve new conditional exemptions from the requirement to obtain a permit, which is currently done by amending the regulations.

APHIS is seeking public comment on the proposed rule. APHIS will consider all public comments submitted during the comment period (which ends November 24) before any regulatory changes are put in place. Because the public is a key partner in the rulemaking process, APHIS scheduled three public meetings to take place in California on Oct. 28, in Missouri on Oct. 30 and the Washington, D.C., area on Nov. 13, to allow interested parties to express their views in person.

- Fact Sheet<sup>2</sup>

- Stakeholders announcement<sup>3</sup>

- Fact Sheet: Qs & As<sup>4</sup>

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<sup>1</sup> <http://www.aphis.usda.gov/newsroom/content/2008/10/brs340.shtml>

<sup>2</sup> [http://www.aphis.usda.gov/publications/biotechnology/content/printable\\_version/fs\\_brs\\_340.pdf](http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/fs_brs_340.pdf)

<sup>3</sup> [http://www.aphis.usda.gov/publications/biotechnology/content/printable\\_version/sa\\_brs340.pdf](http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/sa_brs340.pdf)

<sup>4</sup> [http://www.aphis.usda.gov/publications/biotechnology/content/printable\\_version/faq\\_brs340.pdf](http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/faq_brs340.pdf)

## **U.S. Response to the Global Food Crisis: Humanitarian Assistance and Development Investments<sup>5</sup>**

On July 16, U.S. Agency for International Development (USAID)'s acting Deputy Administrator, made a statement before the Committee on Agriculture U.S. House of Representatives. Extracts from this presentation follow: (...) "We must expand development and use of modern technology for staple foods. We know that we can double yields of staple foods by ensuring that small-holder producers access the tools of modern agriculture - improved seeds, fertilizer, irrigation, dairy management. (...) Through our universities and industry, we are global leaders in the area of science and technology. U.S. farmers are in the forefront of adoption of modern technologies and practices. We see this very clearly in the area of biotech crops, for example. We must dramatically expand the use of existing technology and practices by small farmers (...). To do this, we are expanding funding for research and development, harnessing traditional breeding, biotechnology, geospatial technology to guide resources management, as well as consider the role of advances in nanotechnology and energy efficiency." (...)

### **US encourages countries to lift barriers to biotech<sup>6</sup>**

Last June, Deputy Secretary of State John Negroponte urged countries to remove barriers to the use of biotechnology and other innovations that would increase food production at a time of crisis. He said "We must address the policies and trade barriers that increase food prices by preventing access to food and to the best technologies available to produce food. In the long term, we believe sustainable food security will come from advances in science and technology and the creation of an efficient global market for both agriculture products and food production technologies. We therefore are strongly encouraging countries to remove barriers to the use of innovative plant and animal production technologies, including biotechnology.

Biotechnology tools can help speed the development of crops with higher yields, higher nutrition value, better resistance to pests and diseases, and stronger food system resilience in the face of climate change."

## **2. Economic Perspectives :**

### **2008 Biotech Plantings in the U.S.<sup>7</sup>**

On June 30, the National Agricultural Statistical Service (NASS) published the results of its annual survey on the share of biotech varieties out of the total acreage of corn, soybeans and cotton.

According to NASS, GE crops now represent 80 percent of the total corn acreage, half of which being stacked gene varieties combining resistance to insects and herbicides. NASS estimated that 86 percent of cotton plantings are genetically engineered, again half of this consisting of stacked varieties. Finally, 92 percent of soybean acreage in 2008 consists of herbicide resistant varieties.

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<sup>5</sup> <http://www.usaid.gov/press/speeches/2008/ty080716.html>

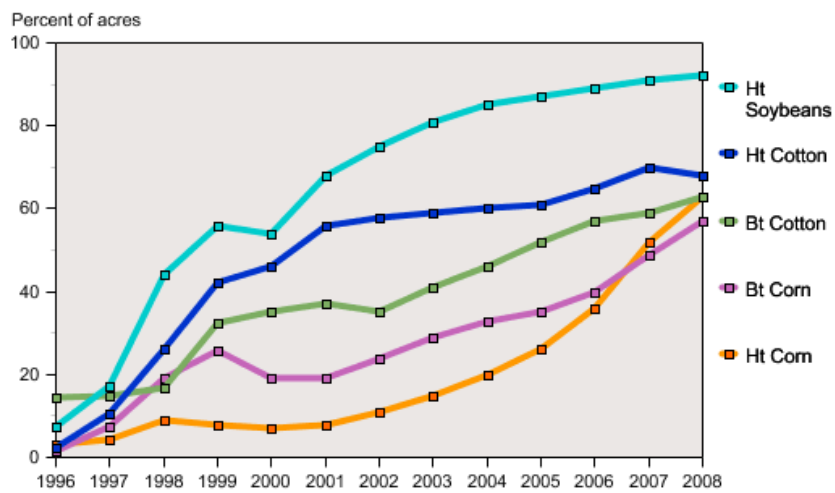
<sup>6</sup> <http://www.state.gov/s/d/2008/105999.htm>

<sup>7</sup> <http://usda.mannlib.cornell.edu/usda/nass/Acre/2000s/2008/Acre-06-30-2008.pdf>

## Adoption of Genetically engineered crops in the U.S.<sup>8</sup>

On July 2, USDA/ERS (Economic Research Service) released a report on the adoption of GE crops in the U.S. since 1996. According to this report, U.S. farmers have adopted genetically engineered (GE) crops widely since their introduction in 1996. Soybeans and cotton genetically engineered with herbicide-tolerant traits have been the most widely and rapidly adopted GE crops in the U.S., followed by insect-resistant cotton and corn. This graph summarizes the extent of adoption of herbicide-tolerant and insect-resistant crops since their introduction in 1996.

### Rapid growth in adoption of genetically engineered crops continues in the U.S.



Data for each crop category include varieties with both HT and Bt (stacked) traits.  
Source: 1996-1999 data are from Fernandez-Cornejo and McBride (2002). Data for 2000-08 are available in tables 1-3.

Tables by crop: Corn<sup>9</sup>, cotton<sup>10</sup>, soybean<sup>11</sup>, all tables in Excel workbook<sup>12</sup>

See more on the extent of the adoption<sup>13</sup>.

## IFPRI Economics Literature on GE Crops Impacts in Developing Economies<sup>14</sup>

bEcon—a web-based bibliography developed by researchers at the International Food Policy Research Institute (IFPRI)—is a selective collection of peer-reviewed applied economics literature that assesses the impacts of genetically engineered (GE) crops in developing countries. The webibliography focuses on four major research questions addressed in the literature: What are the advantages of genetically engineered crops for farmers? What are consumers willing to pay for non-GE products, and how will their preferences affect the market? What are the magnitude and distribution of the economic benefits resulting from the adoption of GE crops in a particular industry? What is the international distribution of economic benefits resulting from the adoption and trade of GE crops?

<sup>8</sup> <http://www.ers.usda.gov/Data/BiotechCrops/>

<sup>9</sup> <http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable1.htm>

<sup>10</sup> <http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable2.htm>

<sup>11</sup> <http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable3.htm>

<sup>12</sup> <http://www.ers.usda.gov/Data/BiotechCrops/alltables.xls>

<sup>13</sup> <http://www.ers.usda.gov/Data/BiotechCrops/adoption.htm>

<sup>14</sup> <http://www.ifpri.org/pubs/bEcon/bEcon.asp>

### 3. International organizations

#### **FAO: Farmers urged to join “Greener” Revolution<sup>15</sup>**

In July, some 100 delegates from 36 countries meeting at FAO called on farmers to join the ongoing “Greener” revolution represented by a form of farming known as Conservation Agriculture (CA). This farming system aims to help feed the world more sustainably by building up soil ecosystems and reducing unnecessary soil disturbance wherever possible. According to one study, some 20 percent of the earth’s cropland is now being eroded or otherwise degraded. Rebuilding good soil structure and encouraging biological processes in soil increases its capacity to produce crops, the delegates declared in a Framework for Action adopted at the end of a three-day technical meeting on Investing in Sustainable Crop Intensification and Improving Soil Health. They urged “a rapid shift, whenever and wherever conditions permit it, to management systems based on minimal soil disturbance, increased soil cover, and appropriate crop rotation”.

#### **Biotechnology Policy Documents of FAO Members<sup>16</sup>**

This webpage of the FAO Biotechnology website brings together biotechnology policy documents from FAO members (currently with 189 Member Nations plus the European Community). The majority are national policy documents, but regional (within country) documents are also included. This page was last updated in July 2008.

#### **OECD: The Bioeconomy to 2030<sup>17</sup>**

The concept of a bioeconomy covers a broad range of economic activities, each benefiting from new discoveries, and the related products and services arising out of the biosciences. The futures project, which will run until end-2008, assesses how pervasive biotechnological applications are likely to become, the prospects for further development over the next two to three decades, the potential impact on the economy and society, and the policy agenda needed to promote and diffuse this new wave of innovations in a way that is consistent with broader socioeconomic goals.

### 4. Scientific Research:

#### **Herbicide-tolerant crops can improve water quality<sup>18</sup>**

The results of a four-year program conducted by USDA/ARS were published in March in the Journal of Environmental Quality under the title “Impact of Glyphosate-Tolerant Soybean and Glufosinate-Tolerant Corn Production on Herbicide Losses in Surface Runoff.” Residual herbicides used in the production of soybean and corn are often detected in surface runoff at concentrations exceeding their maximum contaminant levels (MCL) or health advisory levels. With the advent of transgenic, glyphosate-tolerant soybean and glufosinate-tolerant corn, this concern might be reduced by replacing some of the residual herbicides with short half-life, strongly sorbed, contact herbicides.

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<sup>15</sup> <http://www.fao.org/newsroom/en/news/2008/1000900/index.html>

<sup>16</sup> <http://www.fao.org/biotech/country.asp>

<sup>17</sup> [http://www.oecd.org/document/56/0,3343,en\\_2649\\_36831301\\_36960312\\_1\\_1\\_1\\_1\\_00.html](http://www.oecd.org/document/56/0,3343,en_2649_36831301_36960312_1_1_1_1_00.html)

<sup>18</sup>

<http://jeq.scijournals.org/cgi/content/abstract/37/2/401?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=shipitalo&andorexacttitle=and&titleabstract=herbicide&andorexacttitleabs=and&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT>

## **USDA Scientists Unlock the Key to Rice Nutrition<sup>19</sup>**

New research, funded by USDA's Cooperative State Research, Education, and Extension Service (CSREES), may allow scientists to improve the nutritional value of rice. Researchers determined that chromatin plays an essential role in the control of endosperm sizes and grain quality. The results obtained in this study are applicable not only to rice, but other cereal crops as well in improving grain yield and nutritional quality. The scientists used a new approach called proteomics, which examines proteins in a large scale, to gain new insight into the chromatin structure and function in rice.

## **SemBioSys eligible to proceed with Phase I/II safflower-produced insulin trial<sup>20</sup>**

On September 16, SemBioSys Genetics Inc., a biotechnology company developing a portfolio of therapeutic proteins for metabolic and cardiovascular diseases, announced that it is eligible to proceed with its planned Phase I/II human clinical trial of plant-produced insulin now that the 30-day review period of its Investigational New Drug (IND) application has passed. SemBioSys submitted the application in July to the U.S. Food and Drug Administration (FDA), which has now completed its review of the file. SemBioSys intends to conduct the Phase I/II insulin trial in Europe.

## **Scientists Identify Fungal Disease Culprits with Molecular Genetics<sup>21</sup>**

A new method that rapidly detects the "genetic fingerprints" of fungi responsible for millions of dollars in losses in western wheat has been developed by ARS scientists. Though not ready for commercial use, the real-time quantitative polymerase chain reaction (PCR) assays set the stage for building a comprehensive risk-management database that will help farmers decide the best way to counter the fungi, based on how many of them are present in the soil, as well as other factors such as prevailing conditions, the type of crop grown, and other variables. ARS researchers developed the assays, which now detect 10 *Pythium* and seven *Rhizoctonia* species, and explored the assays' commercial potential and eventual use in gathering fungal data for the risk-management system.

## **Countering Insect Resistance with Designer Bt Toxins<sup>22</sup>**

For decades, Bt toxins were used successfully in organic and mainstream agriculture. With funding from Cooperative State Research, Education, and Extension Service (CSREES), researchers in Arizona and Mexico have collaborated to design, create and test genetically-modified Bt toxins that kill insects resistant to standard Bt toxins. They determined that lab-selected resistance to Cry1A toxins in pink bollworm (*Pectinophora gossypiella*), a major cotton pest in the southwestern United States, is tightly linked with specific genetic mutations. These mutations occur in a gene that carries instructions for making a receptor protein called cadherin that binds Cry1A toxins. The researchers determined that resistance to Bt toxin occurs when mutations inhibit the cadherin gene from properly binding with Cry1A.

## **Purdue and Indiana University collaborating on major life sciences initiative<sup>23</sup>**

In June, Indiana University and Purdue University announced that they will jointly ask the 2009 General Assembly to create a broad-based research alliance that will help the state grow its bio- and life-sciences industries, improve public health and increase the number of physicians being trained in Indiana. The

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<sup>19</sup> [http://www.csrees.usda.gov/newsroom/impact/2008/nri/07281\\_rice\\_nutrition.html](http://www.csrees.usda.gov/newsroom/impact/2008/nri/07281_rice_nutrition.html)

<sup>20</sup> <http://micro.newswire.ca/release.cgi?rkey=1609164896&view=36078-0&Start=0>

<sup>21</sup> <http://www.ars.usda.gov/is/pr/2008/080728.htm>

<sup>22</sup> [http://www.csrees.usda.gov/newsroom/impact/2008/nri/07071\\_bt\\_toxin.html](http://www.csrees.usda.gov/newsroom/impact/2008/nri/07071_bt_toxin.html)

<sup>23</sup> <http://www.envision.purdue.edu/pdfs/papers/I-Light+Collaboration.pdf>

Indiana Innovation Alliance would be led by Purdue and IU and would bring together a wide spectrum of businesses, government and universities to share research facilities and other resources to expand the state's capacity to support new and existing companies in the biology and health-related fields. Research focuses of the alliance would encompass medical and health-related fields, pharmaceuticals, bioenergy and biofuels, nanotechnology, health-care delivery and the environment.

### **USDA/ARS produces online databases for maize genome<sup>24</sup>**

The objective of this project is to develop a next-generation maize genome database, which will be publicly accessible to users via the Web and will serve as a model for data integration and database architecture for other species. ARS scientists have produced several online bioinformatics resources to support plant breeders and other scientists who research genetic traits among plant species. Bioinformatics is a field of science in which biology, computer science and information technology merge to form a single discipline.

### **Plant genetic transformation mechanisms emerge<sup>25</sup>**

With funding from USDA's CSREES, a project team systematically investigates and uncovers fundamental biological principles behind the action of Agrobacterium. To genetically transform plants, Agrobacterium transports its genetic material, in a form of a nucleic acid-protein complex termed the T-complex, into the host cell nucleus. Once inside the nucleus, the T-complex must reach the host chromosomes to complete the integration into the genetic material of the host cell. Agrobacterium employs a diverse number of biological processes to genetically transform the host cell.

### **ARS, Mars and IBM to Sequence the Cacao Genome<sup>26</sup>**

On June 26, a new partnership was announced between ARS, Mars Inc., and IBM with the goal of sequencing the entire cacao genome. Once completed, the research results will be released into the public domain. In addition to the three major partners, Washington State University will assist in developing detailed genetic maps and assembling the sequence fragments into the complete genome sequence. During the past 15 years, the global cocoa industry has confronted a trio of devastating fungal diseases that cost growers an estimated \$700 million in losses annually. Now scientists at ARS are developing productive cacao trees resistant to these diseases: witches' broom, frosty pod and black pod.

## **5. Biotech Industry Perspectives:**

### **Perspectives for RoundUp Ready 2 Soybean (MON89788):**

- Monsanto Announces Key Regulatory Approvals for Roundup Ready 2 Yield™ Soybeans; Product Remains on Track for 2009 Launch<sup>27</sup>

Monsanto Company announced in July 24 that it has received regulatory approvals for Roundup Ready 2 Yield™ soybeans in Mexico, Australia and New Zealand. In addition, the company noted the European Food Safety Authority (EFSA) has issued a positive scientific opinion concluding Roundup Ready 2 Yield

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<sup>24</sup> [http://www.ars.usda.gov/research/projects/projects.htm?ACCN\\_NO=408344](http://www.ars.usda.gov/research/projects/projects.htm?ACCN_NO=408344)

<sup>25</sup> [http://www.csrees.usda.gov/newsroom/impact/2008/nri/08041\\_agrobacterium.html](http://www.csrees.usda.gov/newsroom/impact/2008/nri/08041_agrobacterium.html)

<sup>26</sup> <http://www.ars.usda.gov/is/pr/2008/080626.htm?pf=1>

<sup>27</sup> <http://monsanto.mediaroom.com/index.php?s=43&item=622>

is safe for import as food or feed. Roundup Ready 2 Yield soybeans are the second generation of the popular Roundup Ready® technology in soybeans and offer increased yields.

Monsanto's Roundup Ready 2 Yield soybeans will be introduced on 1 million to 2 million acres for the 2009 season as part of a controlled commercial release, followed by a large-scale product launch of 5 million to 6 million acres scheduled for 2010.

### **- Monsanto and Syngenta Reach Royalty-Bearing Licensing Agreement on Roundup Ready 2 Yield Soybean Technology<sup>28</sup>**

Monsanto expanded on May 23 the potential commercial availability of its breakthrough Roundup Ready 2 Yield™ soybean technology by granting a global royalty-bearing license to Syngenta for use across its soybean seed brands. Monsanto's Asgrow® brand and American Seeds Inc. companies' brands are preparing for the introduction of this higher-yielding soybean technology, and the company is also broadly offering the technology to its Corn States customers to further expand the reach at the time of introductory launch in 2009.

With Syngenta's agreement to terms for a Roundup Ready 2 Yield license, Monsanto now estimates a potential available acreage for the product of 45 million to 55 million acres in the United States, or an increase of more than 10 percent over its original projection of 40 million to 50 million acres. Monsanto believes that Roundup Ready 2 Yield ultimately could be used on approximately seventy-five percent of an average of 60 million to 70 million soybean acres in the United States. Sales of Syngenta's brands represented approximately 12 percent of total U.S. soybean sales in 2007. Monsanto's Asgrow and American Seeds Inc. brands collectively represented approximately 27 percent of total U.S. soybean sales in 2007.

### **New Pioneer Soybean varieties:**

#### **- U.S. Approval of Optimum® GAT® Trait<sup>29</sup>**

On July 17, DuPont announced that it has received United States regulatory approval of its proprietary herbicide tolerance trait, the Optimum® GAT® trait in soybeans. Pioneer Hi-Bred recently launched its new high-yielding Y Series soybean varieties for 2009. The first-ever agricultural trait developed through proprietary DuPont gene shuffling technology, the Optimum® GAT® trait will provide broader spectrum weed control without compromising crop safety. This includes the ability to incorporate complementary ALS herbicides into a glyphosate program, including the new DuPont™ Freestyle™, Traverse™, Instigate™ and Diligent™ herbicides that DuPont Crop Protection has developed and is demonstrating in test plots this year.

#### **- New Y Series Pioneer® Brand Low Linolenic Soybeans for 2009<sup>30</sup>**

The new low linolenic soybeans in the Y Series line have shown yield advantages over previous low linolenic products. The new Pioneer low linolenic soybean products offered to growers in 2009 will include varieties featuring higher yields and excellent defensive traits: 92Y90 offers very good tolerance to brown stem rot and has very good emergence and stability scores under a wide range of environments; 93Y01 is an early Group III variety featuring good field emergence and harvest standability; 93Y50 is a high-

<sup>28</sup> <http://monsanto.mediaroom.com/index.php?s=43&item=604>

<sup>29</sup> <http://www.pioneer.com/web/site/portal/menuitem.7cc7454c0d46e81322712271d10093a0/>

<sup>30</sup> <http://www.pioneer.com/web/site/portal/menuitem.e4fc36bb95efe8f8e5c3e5c3d10093a0/>

yielding new variety that displays strong field emergence and harvest standability, plus resistance to Phytophthora root rot. In its fifth year, this low linolenic soybean contracting program has grown from a targeted base in Iowa to an expanded geography currently reaching multiple locations in at least seven states for the 2009 growing season: Iowa, Illinois, Indiana, Ohio, Michigan, Pennsylvania and Missouri.

## Insurance Premiums for Biotech Crops:

In September 2007, USDA/RMA (Risk Management Agency) launched a pilot program called Biotech Yield Endorsement for the 2008 crop year in the states of Illinois, Indiana, Iowa, and Minnesota (see February 2008 biotech newsletter<sup>31</sup>). In 2008, the BYE provided producers a premium rate reduction if they plant non-irrigated corn for grain containing three specific biotech traits - YieldGard® Corn Borer, YieldGard Rootworm and Roundup Ready® Corn 2.

In August 2008, this program was renamed the program the Risk Management Biotechnology Endorsement (BE), and expanded to more States (Kansas, Michigan, Missouri, Nebraska, Ohio, South Dakota, and Wisconsin) in addition to the initial four pilot states of Illinois, Indiana, Iowa and Minnesota. Also, more biotech varieties will be grown for the 2009 crop year. Responses to this initiative include the following:

- DuPont Obtains Biotechnology Endorsement for Pioneer® Brand Products<sup>32</sup>
- Kansas, Nebraska Corn Farmers Eligible for Premium Savings<sup>33</sup>
- Corn Farmers Who Use Monsanto Advanced Technology Eligible for Lower Risk Insurance Premiums<sup>34</sup>

## 6. Background information:

- U.S. regulatory framework: <http://usbiotechreg.nbii.gov>
- List of regulated and deregulated products:  
[http://www.aphis.usda.gov/biotechnology/brs\\_main.shtml](http://www.aphis.usda.gov/biotechnology/brs_main.shtml)  
[http://www.aphis.usda.gov/brs/not\\_reg.html](http://www.aphis.usda.gov/brs/not_reg.html)
- Adoption of biotechnology and its production impacts:  
<http://www.ers.usda.gov/Data/BiotechCrops/>

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**NEW!**

<sup>31</sup> <http://www.usda-france.fr/media/bulletinfebruary2008.pdf>

<sup>32</sup> <http://www.pioneer.com/web/site/portal/menuitem.703ed987e71feabdcfe6cfe6d10093a0/>

<sup>33</sup> <http://monsanto.mediaroom.com/index.php?s=43&item=635>

<sup>34</sup> <http://monsanto.mediaroom.com/index.php?s=43&item=628>